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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/699,076	10/27/2000	Nicos A. Petasis	06666/005002	9032
26181	7590	11/04/2005	EXAMINER	
FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022			SHIBUYA, MARK LANCE	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/699,076	PETASIS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Mark L. Shibuya	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 12,18-21,29 and 34-44 is/are pending in the application.
- 4a) Of the above claim(s) 34 and 40-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12,18-21,29,35-39,43 and 44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

The following Office action was returned to the USPTO and marked as undelivered, entered 3/10/2005. In regards to an Office action returned to the Office by the US Postal Service, the MPEP states:

### 707.13 Returned Office Action [R-2]

Office actions are sometimes returned to the Office because the United States Postal Service has not been able to deliver them. The examiner should use every reasonable means to ascertain the correct address and forward the action again, after stamping it "remailed" with the date thereof and redirecting it if there is any reason to believe that the action would reach applicant at such new address. If the Office action was addressed to an attorney, a letter may be written to the inventor or assignee informing him or her of the returned action. The period running against the application begins with the date of remailing. Ex parte Gourtoff, 1924 C.D. 153, 329 O.G. 536 (Comm'r Pat. 1924).

If the Office is not finally successful in delivering the letter, it is placed, with the envelope, in the file wrapper. >For an Image File Wrapper (IFW), a copy of the letter, and a copy of the envelope should be added to the IFW (see IFW Manual).< If the period dating from the remailing elapses with no communication from applicant, the application is abandoned.

### MPEP 707.13.

Upon request, applicant has filed a change of address, entered 9/21/2005.

Pursuant to MPEP 707.13, the following Office action should be considered as stamped "remailed", with the period running against the application beginning from the date of remailing. The Office action follows below.

Art Unit: 1639

1. Claims 12, 18-21, 29 and 34-44 are pending. Claims 34 and 40-42 are withdrawn. Claims 12, 18-21, 29, 35-39, 43 and 44 are examined.

***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/8/2004 has been entered.

***Election/Restrictions***

3. The Requirement for Election/Restrictions, as set forth and considered in Office actions mailed 10/10/2001, 3/27/2002, 10/17/2002 and 3/26/2003; and applicant's election of Group I (originally claim 12), without traverse, is maintained. Reservations regarding applicant's election of species, as discussed in the Office action, mailed 3/26/2003, are noted for the record.
4. Claims 34 and 40-42 remain withdrawn from further consideration as being drawn to non-elected species, there being no allowable generic or linking claim.

### **Withdrawn Claim Rejections**

5. The rejection of claim 38 under 35 U.S.C. 112, first paragraph, for new matter, is withdrawn in view of applicant's amendment to the claim, filed 9/8/2004.

### **Maintained Claim Rejections**

#### ***Maintained Claim Rejections - 35 USC § 102/103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 12, 18-21, 29, 35-39, 43 and 44 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Palfreyman et al., US 4,421,767. This rejection maintains the reasons of record, as set forth in the previous Office actions, mailed 11/12/2003 and 3/26/2003. The rejection of claim 44 is necessitated by applicant's addition of claim 44, filed 9/8/2004.

#### ***Response to Arguments***

Applicant's arguments filed 9/8/2004 have been fully considered but they are not persuasive. Applicant argues that the reference of Palfreyman et al., US 4,421,767, does not disclose a combinatorial library, as defined in the instant application. Applicant argues that Palfreyman does not disclose a collection of compounds as instantly claimed, but instead discloses individual compounds represented as a Markush group. Applicant states that the compounds in the claimed library are related by location and by preparation. Applicant states that individual compounds disclosed as formula I, II or III in Palfreyman, does not disclose a collection as claimed in instant claim 12.

Applicant further argues that Palfreyman does not provide any teaching or suggestion to do that which applicant has done. Applicant argues that Palfreyman discloses individual compounds by formula I, II or III in a Markush format, and individual compounds are not the same as a collection of compounds or a combinatorial library, as claimed.

Applicant further states that "the combinatorial library of the instant claims encompasses **mixtures of compounds and a collection of individual, pure compounds** prepared by the process recited in the claim. The claim is **not directed to individual compounds.**" Applicant argues that the instant claim recites the feature that the plurality of compounds in the combinatorial library are prepared by the process recited in the claim. Again, applicant states that the library can be made as a mixture of compounds, or as a collection of individual pure compounds, depending on the methods used for identification of active compounds. Applicant states "[w]hen the library is made as a mixture of compounds, the compounds in the library are related by location as members of a common mixture having unique chemical and/or physical characteristics. When the library is made as a collection of individual pure compounds, the compounds are related by location as individual compounds distributed in a combinatorial array." Applicant states that upon amendment, claim 12 now recites the limitation that the plurality of compounds in the combinatorial library are prepared by the process recited in the claim.

Applicant's arguments have been considered, but are not deemed persuasive. The examiner respectfully submits that the patent reference of Palfreyman discloses a

Art Unit: 1639

collection of individual pure compounds. These compounds of Palfreyman are related in that they share a common core structure that confers a common property, as demonstrated by the common purpose to which they may be put, i.e., treatment of mental depression. The reference of Palfreyman discloses anticipatory compounds I, II and III together, and contemplates treating patients with any one of compounds I, II or III. The examiner respectfully submits that, as such, Palfreyman discloses compounds I, II and III as an ensemble of molecules, sharing a method of synthesis, molecular core structure, properties, and purpose. Even although applicant argues that Palfreyman does not teach a "library" of compounds; however, the term is used quite broadly in the art to mean "any ensemble of molecules" (e.g., see Janda, K.D. "Tagged versus untagged libraries: Methods for the generation and screening of combinatorial chemical libraries", Proc. Nat'l. Acad. Sci., USA, November 1994, 91, 10779-10785, especially p. 10779, column 1, last sentence, "In its purest form, a combinatorial chemical library can be defined as any ensemble of molecules"). Therefore the examiner respectfully submits that the reference of Palfreyman et al. disclose a combinatorial library of compounds I, II and III.

Applicant's traversal of the instant rejection, as understood by the examiner, appears to argue that the compounds of a library must be related by location, as either in a mixture, or distributed in an array. These limitations are not required in the description of the term "combinatorial library", found in the specification as filed at p. 7, lines 14-36, although the specification teaches such mixtures or arrays may be preferred. For example, the specification, at p. 7, state that "it may be preferred to

Art Unit: 1639

provide the library as a large mixture of compounds", or that "[l]arge combinatorial libraries may also be prepared by massively parallel synthesis of individual compounds, in which case compounds are typically identified by their position within an array."

Therefore, the examiner respectfully submits that these limitations are not found in the claims, and are precatory in the specification's description of combinatorial libraries. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., libraries must have compounds as mixtures or arrays) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Furthermore, it would have been obvious for one of ordinary skill in the art to have combined the compounds taught by Palfreyman, and thereby form a combinatorial library, because said compounds are used for a common purpose, i.e., the treatment of mental depression. See *In re Kerhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (stating: "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art" [citations omitted]); and MPEP 2144.06.



### **New Claim Rejections**

#### ***New Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 12, 18-21, 29, 35-39, 43 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12 and 44 recite the limitation "the compound" in the last line. There is uncertain antecedent basis for this limitation in the claims.

#### ***New Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

Art Unit: 1639

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 12, 18-21, 29, 35-39, 43 and 44 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kick et al., J. Med. Chem. 1995, 38, 1427-1430.

Kick et al. disclose collections of compounds (reading on the claimed "combinatorial library") that read directly on the instant formula 1. See, compounds 7a, 7b and 7c in Kick et al., (p. 1428, para 3 and Figure 2). The compounds of the reference read on the claims wherein R<sup>1</sup> is hydrogen, R<sup>2</sup> is carboxamido, R<sup>3</sup> and R<sup>4</sup> are independently hydrogen, and R<sup>5</sup> is heteroaryl.

In the alternative, although Kick et al., does not disclose that their collections of compounds (i.e. libraries) are made by the claimed process, the products of Kick et al. would appear to be the same as those recited by the instant claim, regardless of their method of manufacture. See MPEP 2113. Also note that many of the instant claims recite only process limitations and thus are non-limiting on the product.

The collection of compounds of Kick et al. (reading on the claimed "combinatorial library") meet all of the limitations of the claimed library except for the product-by-process limitations and would either anticipate or render obvious the claimed library. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is

Art Unit: 1639

unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

The examiner respectfully submits that because the claim is drawn to a “combinatorial library”, but this product is defined as a product-by-process, that any collection of compounds meeting the structural requirements of the instant claims reads on this product. The process by which the claimed library is made does not appear to lend patentable weight to the claimed invention. One of ordinary skill would expect the library to be the same no matter how it was synthesized.

9. Claims 12, 18-21, 29, 35-39, 43 and 44 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gordon et al., Bioorganic & Medicinal Chemistry Letters, 1995, Vol. 5, No. 1, pp. 47-50.

Gordon et al. disclose collections of compounds (reading on the claimed “combinatorial library”) that read directly on alpha-amino acid derivatives of the formula depicted in claim 37. See, the compounds of the Tables found on p. 48 of Gordon and Scheme 2 on p. 49, and the text on said pages. Gordon et al. teach ten different alpha amino acids, which are then attached to resin bead, and mixed, providing a combinatorial library of alpha amino acids. These compounds of the reference read on the claims where the combinatorial library contains alpha amino acids.

In the alternative, although Gordon et al., does not disclose that their collections of compounds (i.e. libraries) are made by the claimed process, the products of Gordon et al. would appear to be the same as those recited by the instant claim, regardless of

Art Unit: 1639

their method of manufacture. See MPEP 2113. Also note that many of the instant claims recite only process limitations and thus are non-limiting on the product.

The collection of compounds of Gordon et al. (reading on the claimed "combinatorial library") meet all of the limitations of the claimed library except for the product-by-process limitations and would either anticipate or render obvious the claimed library. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

The examiner respectfully submits that because the claim is drawn to a "combinatorial library", but this product is defined as a product-by-process, that any collection of compounds meeting the structural requirements of the instant claims reads on this product. The process by which the claimed library is made does not appear to lend patentable weight to the claimed invention. One of ordinary skill would expect the library to be the same no matter how it was synthesized.

### ***Conclusion***

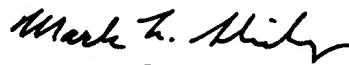
10. Claims 12, 18-21, 29, 35-39, 43 and 44 are rejected. Claims 34 and 40-42 are withdrawn.

Art Unit: 1639

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark L. Shibuya  
Examiner  
Art Unit 1639

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